California Medical Device Recall Information

Recall Name
Alere Recalls INRatio® and INRatio®2 PT/INR Monitor System Due to Incorrect Results

Recall Date	Product Description	Recalling Firm	Recall Reason
Updated: 12/08/14 Initial: 04/16/14	• INRatio®2 PT/INR Monitors • INRatio® PT/INR Monitors • INRatio® PT/INR Test Strips	**Alere, Inc.** San Diego, CA	*In certain cases an INRatio® and INRatio®2 PT/INR Monitor System may provide inaccurate INR results.* *Issues can arise if the patient has certain medical conditions or if the System instructions in the labeling for performing the test are not followed.*
Recall Class	**Product Identification**	**Distribution**	**Affected Dates**
I	**All** INRatio® PT/INR test strips and monitors. Product Photos	**CA**, nationwide	Test strips distributed from: September 4, 2013 to December 4, 2014. Monitors were distributed from: April 2008 to December 3, 2014.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm426166.htm